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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/329,002	06/08/1999	CHARLES R. MOONEY	ECC-5062CIP2	7619
30452	7590	02/13/2004	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION			THANH, LOAN H	
ONE EDWARDS WAY			ART UNIT	
IRVINE, CA 92614			PAPER NUMBER	
			3763	

DATE MAILED: 02/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/329,002

Applicant(s)

MOONEY ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37, 60-80, 86 and 87 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 19, 25 and 71-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 21, 26-29, 53, 60, 62, 76, 79, 86 and 87 is/are rejected.
- 7) ☒ Claim(s) 4-11, 17-18, 20, 22-24, 30-37, 61, 63-70, 75, 77-78, 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>28-29</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

The claim rejection under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs has been obviated in view of the amendment filed 10/20/03.

The specification objection has been obviated in view of the amendment filed 10/20/03.

### ***Claim Objections***

Claims 30-37 are objected to because of the following informalities: Applicant is to include what element the junction housing is softer than. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 recites the limitation "the distal ends of two auxiliary lumens" in line 1-2. There is insufficient antecedent basis for this limitation in the claim. However there is antecedent basis in claim 75.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,21,26,27,28,29,60,62,79,87 are rejected under 35 U.S.C. 102(b) as being anticipated by Walling ( U.S. Patent No. 4,233,984) or Frassica ( U.S. Patent No. 5,318,532).

Walling discloses a multiple lumen access system comprising an outer tube , a device lumen m an auxiliary lumen a flexible wall wherein the outer wall is relatively stiff relative to the flexible wall 40. Walling discloses the outer tube to be a suitable polymeric material and the flexible wall/ septum to be a suitable rubber or plastic. See figures 1-7. See columns 2-4.

Frassica discloses a multiple lumen access system. See figures1-7a. The auxiliary lumen being the lumen where the fluid is introduced and the medical device lumen is element 26. The flexible wall is 24/50. See abstract , columns 2, 4-8.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 63,86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walling (U.S. Patent No. 4,233,984).

Walling discloses a multiple lumen access system as substantially claimed. See above. Walling further discloses the conventional port valves used with the pilot tubes. However, Walling is silent to the auxiliary and device lumen valves. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the auxiliary and device lumen as disclosed by Walling in order to provide a hemostatic valve to prevent introduction or leakage of fluid in the claimed lumen.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-11,17-18, 20-24, 26-37, 60-70, 78-80 filed 10/20/03 have been considered but are moot in view of the new ground(s) of rejection.

Palestrant has not been applied since Walling provided a better rejection. However Palestrant would now read on at least the independent claims 1, 60 since the outer tube is relatively stiff in relation to the flexible wall.

### ***Allowable Subject Matter***

Claims, 418,20,22-24,30-37,61,63-70,75,77-78,80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

LoAn H. Thanh  
Examiner  
Art Unit 3763

LT

A handwritten signature in black ink, appearing to read 'Loan H. Thanh', with a long horizontal flourish extending to the right.

**LOAN H. THANH**  
**PRIMARY EXAMINER**